LEWIS &
HARRISON
Consultants in Government Affairs

122 C Street, N.W., Suite 505
Washington, D.C. 20001
telephone 202.393.3903
fax 202.393.3906

July 11, 2016

Stephen Savage
Chemical Review Manager
Antimicrobials Division (7510P)
Office of Pesticide Programs
Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

re: Hexahydro-1,3,5-tris (2-hydroxymethyl)-s-triazine (HHT)
Generic Data Call-In (GDCI) No. 083301-1554
Request for Meeting

Dear Mr. Savage:

On behalf of several registrants (Lonza Inc. Buckman Laboratories, Troy Chemical Company, Stepan Company and Surety Laboratories) that are subject to the GDCI for HHT, I am requesting that a meeting be scheduled to discuss the GDCI.

Subsequent to the issuance of the Final Work Plan for HHT and the GDCI, Troy Chemical Company received the results of a detailed and comprehensive chemistry study that evaluated the hydrolysis/degradation of HHT. The results of this work call into question the hydrolysis pathway for HHT that was postulated in the Final Work Plan (FWP) for this substance. On page 10 of the FWP, the Agency assumed that formaldehyde is released from HHT by cleaving carbon-carbon (C-C) bonds. If HHT is degraded in this manner, the degradates will be formaldehyde and 1,3,5-trimethyl triazine. The data collected in the Troy sponsored study clearly demonstrate that cleavage occurs among the carbon-nitrogen bonds. This pathway cleaves the triazine ring and results in formaldehyde and monoethanolamine (MEA). Another key finding is that dilute solutions of HHT are rapidly degraded. Accordingly, any environmental fate, toxicity or exposure studies performed with dilute solutions of HHT will actually be testing a mixture of formaldehyde and MEA. Since there is a substantial safety data base for both formaldehyde and MEA any further testing on HHT will not provide any additional or useful information.

A summary of the hydrolysis/degradation study mentioned above is attached. A complete copy of the study will be submitted through front-end processing. Please note that the study was conducted using nuclear magnetic resonance (NMR). Previous chemistry studies showed that methods specific for formaldehyde (e.g. dinitrophenyl hydrazine derivatization) or high-performance liquid chromatograph (HPLC) are not suitable for the detection of HHT since they destroy the products equilibrium with formaldehyde, resulting in an inaccurate assessment of HHT and its degradates. NMR was chosen due to its non-destructive nature and its ability to capture the true behavior of HHT and formaldehyde.

An agenda for the meeting is also attached.

Sincerely,

Eliot Harrison,
On behalf of Troy Chemical, Lonza Inc,
Stepan Company, Buckman Laboratories,
Surety Laboratories

Agenda for Meeting Between Registrants of Hexahydro-1,3,5-tris (2-hydroxymethyl)-s-triazine (HHT) and Antimicrobials Division Regarding the GDCI for HHT

Date/Time: To be determined
Participants: Buckman Laboratories, Lonza Inc., Troy Chemical Company, Stepan Company and Surety Laboratories

Agenda

1. Recent chemistry studies on HHT
    - Description of the studies
    - Results of the studies

2. Implication of the Chemistry Studies for HHT Testing and Assessments
    - GDCI studies based on pathway outlined in Final Work Plan (FWP)
    - Chemistry studies do not support this pathway
    - Need for conducting GDCI studies if alternative pathway is correct

3. Responding to GDCI
    - Submission of complete chemistry study
    - Waiver requests
    - Amend FWP and reissue GDCI?

GDCI -083301-1554- Toxicology Data Requirements
Data Waiver Request

Data waivers are being required for the following studies:

Guideline Number	***Study Title***
870.6200	Neurotoxicity Screening Battery
870.3485	Metabolism and Pharmacokinetics
870.7800	Immunotoxicity

Basis for Waiver Request

In 2010, HHT registrants met with the Agency to discuss the toxicology data requirements that were part of the Reregistration Data Call-In for HHT. At that time, the Agency agreed that the toxicity of formaldehyde donor products, such as HHT, are directly linked to formaldehyde and agreed the toxicological data requirements for HHT should be held in abeyance until the Science Advisory Panel (SAP) evaluated the updated IRIS document on formaldehyde. The same agreement should be applied to the above toxicology studies.

As with the environmental fate and non-target organisms data requirements discussed above, if the Agency accepts the degradation pathway for HHT as outlined in the submission of July 11 2016, toxicology studies using HHT will essentially be a test of a monoethanolamine + formaldehyde mixture. There is a large toxicology data base on both of these substances so the requested toxicology studies are unlikely to provide any additional useful information. If the degradation data provided on HHT is not sufficient for the Agency to make a determination on the testing requirements for this substance, a bridging study should be considered.

Exposure Data Requirements

Data waivers are being requested for the following studies:

Guideline Number	Study Title
SS-1218	Nature of the Residue on Surfaces
870.1200	Dermal Exposure Indoor
870.2400	Dermal Exposure-PostApplication
875.1400	Inhalation Exposure-Indoor

Basis for Waiver Request

The nature of the residue on surfaces and migration studies should be waived since these use-sites are not on any of HHT labels registered to Troy Chemical Corporation. In addition Troy Chemical is an active member of the ACC Antimicrobial Exposure Assessment Task Force II responsible for generating exposure data for the Agency for a number of antimicrobial exposure scenarios.

Finally based on the degradate profile dermal exposure studies should be waived since dermal exposure should be based on the HHT degradates formaldehyde and monoethanolamine. Extensisve dermal data on these two substances exist.

Miscellaneous

Troy Chemical Corporation in conjunction with other HHT registrants would like to schedule a meeting with Agency staff, as soon as possible, to discuss the aforementioned hydrolysis studies conducted with HHT, revised IRIS assessment of formaldehyde and the latest information on formaldehyde exposure studies by inhalation.

LEWIS &
HARRISON
Consultants in Government Affairs

122 C Street, N.W., Suite 505
Washington, D.C. 20001
telephone 202.393.3903
fax 202.393.3906

August 8, 2016

Document Processing Desk (DCI/AD)
Antimicrobials Division (7510P)
Office of Pesticide Programs
Environmental Protection Agency
One Potomac Yard (South Building)
2777 S. Crystal Drive
Arlington, VA 22202

Attention: Reevaluation Team Leader, PM#36

re: GDCI-083301-1554
Case #3074
Hexahydro-1,3,5-tris(2-hydroxyethyl)-s-triazine (HHT)
Response to Data Call-In
Registrant: Surety Laboratories (Company No. 68868)

Dear Sir or Madam:

On behalf of Surety Laboratories, I am submitting the following documents in response to the Generic Data Call-In (GDCI) notice for Hexahydro-1,3,5-tris(2-hydroxyethyl)-s-triazine (HHT) that was issued in May, 2016.

- Data Call-In Response Form.
- Requirements Status and Registrant's Response Form and Attachments.

Since there are a some key outstanding issues that involve the GDCI, Surety is requesting that a meeting be scheduled as soon as possible so that these issues can be resolved. A request for a meeting was previously submitted to the Agency (see attachment).

If you have any questions regarding this response, please contact me at (202) 393-3903, ext. 114 or by e-mail at eharrison@lewisharrison.com.

Sincerely,

Eliot Harrison
Agent for Surety Laboratories

United States Environmental Protection Agency
Washington, D.C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

OMB Approval 2070-0174
EPA FORM 6300-3

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company Name and Address	2. Case # and Name	3. Date and Type of DCI and Number
SURETY LABORATORIES 2 STEWART COURT DENVILLE, NJ 07834	3074 - Hexahydro-1,3,5-tris(2-hydroxyethyl)-s-triazine Chemical # and Name: 083301 Hexahydro-1,3,5-tris(2-hydroxyethyl)-s-triazine	06-May-2016 GENERIC ID # GDCI-083301-1554

4. Guideline Requirement Number	5. Study Title		PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
	Nontarget Plant Protection Data Requirements (Conventional Chemical)									
850.4400	Aquatic Plant Toxicity Using Lemna spp	(8)	N				X,Y,Z	TGAI	12	9
	Terrestrial and Aquatic Nontarget Organisms Data Requirements (Conventional Chemical)									
850.1300	Daphnid chronic toxicity test	(8)	N				X,Y,Z	TGAI	12	9
850.1400	Fish early-life stage toxicity test	(8)	N				X,Y,Z	TGAI	12	9
	Toxicology Data Requirements (Conventional Chemical)									
870.6200	Neurotoxicity screening battery	(6, 8, 14)	Y				X,Y,Z	TGAI	12	9
870.7485	Metabolism and pharmacokinetics	(8)	N				X,Y,Z	PAIRA	24	9
870.7800	Immunotoxicity	(8)	N				X,Y,Z	TGAI	12	9

10. Certification: I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative: Geoff Eliot Harrison, Agent for Surety

11. Date: 8-8-2016

12. Name of Company: SURETY LABORATORIES

13. Phone Number: 202 393-3903

ct 114

United States Environmental Protection Agency
Washington, D.C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

OMB Approval 2070-0174
EPA FORM 6300-3

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company Name and Address	2. Case # and Name	3. Date and Type of DCI and Number
SURETY LABORATORIES 2 STEWART COURT DENVILLE, NJ 07834	3074 - Hexahydro-1,3,5-tris(2-hydroxyethyl)-s-triazine Chemical # and Name: 083301 Hexahydro-1,3,5-tris(2-hydroxyethyl)-s-triazine	06-May-2016 GENERIC ID # GDCI-083301-1554

4. Guideline Requirement Number	5. Study Title		PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
835.1110	Activated sludge sorption isotherm	**(5, 8, 11)**	N				X,Y,Z	COMMENT	12	9
835.1230	Sediment and soil absorption/desorption for parent and degradates	**(5, 8)**	N				X,Y,Z	COMMENT	12	9
835.2120	Hydrolysis of parent and degradates as a function of pH at 25 C	**(5, 8)**	N				X,Y,Z	COMMENT	12	2
835.3110	Ready biodegradability	**(1, 5, 8)**	N				X,Y,Z	COMMENT	12	9
835.3220	Porous pot test	**(1, 5, 8)**	N				X,Y,Z	COMMENT	12	9
835.3240	Simulation Test-Aerobic Sewage Treatment-Activated Sludge	**(1, 5, 8)**	N				X,Y,Z	COMMENT	12	9
835.3280	Simulation Tests to Assess the Biodegradability of Chemicals	**(1, 5, 8)**	N				X,Y,Z	COMMENT	12	9
835.4300	Aerobic aquatic metabolism	**(5, 8)**	N				X,Y,Z	COMMENT	24	9
850.3300	Modified Activated Sludge, Respiration Inhibition Test	**(5, 8, 10)**	N				X,Y,Z	COMMENT	12	9

Agent for Surety

8-8-2016

United States Environmental Protection Agency
Washington, D.C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

OMB Approval 2070-0174
EPA FORM 6300-3

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company Name and Address	2. Case # and Name	3. Date and Type of DCI and Number
SURETY LABORATORIES 2 STEWART COURT DENVILLE, NJ 07834	3074 - Hexahydro-1,3,5-tris(2-hydroxyethyl)-s-triazine Chemical # and Name: 083301 Hexahydro-1,3,5-tris(2-hydroxyethyl)-s-triazine	06-May-2016 GENERIC ID # GDCI-083301-1554

4. Guideline Requirement Number	5. Study Title		PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
850.4500	Algal Toxicity	**(7, 8)**	N				X,Y,Z	TGAI	12	9
850.4550	Cyanobacteria (Anabaena flos-aquae) Toxicity	**(7, 8)**	N				X,Y,Z	TGAI	12	9
875.1200	Dermal exposure--Indoor	**(8, 12, 14)**	Y				X,Y,Z	TEP	24	9
875.1400	Inhalation exposure--indoor	**(2, 8, 12, 14)**	Y				X,Y,Z	COMMENT	24	1
875.1700	Product Use Information	**(8)**	N				X,Y,Z	TEP	12	1
875.2400	Dermal exposure	**(3, 8, 14)**	Y				X,Y,Z	TEP	24	9
875.2500	Inhalation exposure	**(2, 8, 9, 14)**	Y				X,Y,Z	COMMENT	24	1
SS-1218	Nature of Residue on Surfaces	**(4, 8, 14)**	Y				X,Y,Z	TGAI	24	1
SS-Migration	Migration studies	**(4, 8, 13, 14)**	Y				X,Y,Z	TEP	12	1

Agent for Surety

8-8-2018

ATTACHMENT TO REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORM

Registrant: Surety Laboratories (Company No. 68868)
Active Ingredient: Hexahydro-1,3,5-tris(2-hydroxyethyl)-s-triazine

Surety Laboratories is requesting that the Agency waive several of the studies listed in the Generic Data Call-In (GDCI) for hexahydro-1,3,5-tris(2-hydroxyethyl)-s-triazine (HHT). The specific data requirements that waivers are being requested for are discussed below. In addition, comments are being provided regarding some of the data requirements for which studies will be submitted.

Environmental Fate and Non-Target Organism Data Requirements

Data waivers are being requested for the following studies:

Guideline Number	Study Title
835.1110	Activated sludge sorption isotherm
835.1230	Sediment and soil absorption/desorption for parent and degradates
835.2120	Hydrolysis of parent and degradates as a function of pH at 25°C
835.3110	Ready biodegradability
835.3220	Porous pot test
835.3240	Simulation test- Aerobic sewage treatment – activated sludge
835.3280	Simulation tests to assess the biodegradability of chemicals
835.4300	Aerobic aquatic metabolism
850.3300	Modified activated sludge, Respiration inhibition test
850.4400	Aquatic plant toxicity using Lemna
850.1300	Daphnid chronic toxicity test
850.1400	Fish early life-stage toxicity test

Basis for Waivers

As discussed in the submission provided to the Agency on July 11, 2016 (attached), HHT is expected to rapidly degrade upon aqueous dilution. The predominant degradates are monoethanolamine and formaldehyde. The substance 1,3,5-trimethyl triazine does not result from the degradation of HHT. Accordingly, the substances present in the environment from the use of HHT will be monoethanolamine and formaldehyde (minor degradates, methanol and 1,3-oxazolidine, might also be present). Therefore, the requested environmental fate and ecotoxicity studies would be actually be testing a mixture of monoethanolamine and formaldehyde, not HHT or 1,3,5-trimethyl triazine. Since there is an ample environmental fate and ecological effects database on monoethanolamine and formaldehyde, conducting additional studies with this mixture will not provide any useful additional data.

The degradation behavior of HHT was evaluated in the hydrolysis study with metal working fluids that was previously submitted to the Agency (MRID No. 48741001) and the study recently submitted by Troy Chemical Company ("HHT Hydrolysis –Evidence on Dissociation"). If there are any issues that remain regarding the degradation of HHT and the resulting degradates, these can be addressed in a follow-up hydrolysis study. In this case, the Agency should reserve the GDCI environmental fate studies until a final determination is made regarding the degradation behavior of HHT.

Toxicology Data Requirements

Data waivers are being required for the following studies:

Guideline Number	Study Title
870.6200	Neurotoxicity Screening Battery
870.3485	Metabolism and Pharmacokinetics
870.7800	Immunotoxicity

Basis for Waiver Request

In 2010, HHT registrants met with the Agency to discuss the toxicology data requirements that were part of the Reregistration Data Call-In for HHT. At that time, the Agency agreed that the toxicity of formaldehyde donor products, such as HHT, are directly linked to formaldehyde and agreed that the toxicological data requirements for HHT should be held in abeyance until the Science Advisory Panel (SAP) evaluated the updated IRIS document on formaldehyde. The same agreement should be applied to the above toxicology studies.

As with the environmental fate and non-target organisms data requirements discussed above, if the Agency accepts the degradation pathway for HHT as outlined in the submission of July 11 2016, toxicology studies using HHT will essentially be a test of a monoethanolamine + formaldehyde mixture. There is a large toxicology data base on both of these substances so the requested toxicology studies are unlikely to provide any additional useful information. If the degradation data provided on HHT is not sufficient for the Agency to make a determination on the testing requirements for this substance, a bridging study or a comparison of the HHT database with formaldehyde and monoethanolamine should be considered.

Exposure Data Requirements

Surety is requesting that the Agency hold the dermal exposure data requirements, as noted below, in abeyance until a determination is made regarding the substances that are associated with dermal exposure from the use of HHT. Surety has previously provided an inhalation study for the detergent use of HHT and will provide a similar study for cleaning products, if necessary.

Guideline Number	Study Title
870.1200	Dermal Exposure Indoor
870.2400	Dermal Exposure- Post Application

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HARRISON
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July 11, 2016

Stephen Savage
Chemical Review Manager
Antimicrobials Division (7510P)
Office of Pesticide Programs
Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

re: Hexahydro-1,3,5-tris (2-hydroxymethyl)-s-triazine (HHT)
Generic Data Call-In (GDCI) No. 083301-1554
Request for Meeting

Dear Mr. Savage:

On behalf of several registrants (Lonza Inc. Buckman Laboratories, Troy Chemical Company, Stepan Company and Surety Laboratories) that are subject to the GDCI for HHT, I am requesting that a meeting be scheduled to discuss the GDCI.

Subsequent to the issuance of the Final Work Plan for HHT and the GDCI, Troy Chemical Company received the results of a detailed and comprehensive chemistry study that evaluated the hydrolysis/degradation of HHT. The results of this work call into question the hydrolysis pathway for HHT that was postulated in the Final Work Plan (FWP) for this substance. On page 10 of the FWP, the Agency assumed that formaldehyde is released from HHT by cleaving carbon-carbon (C-C) bonds. If HHT is degraded in this manner, the degradates will be formaldehyde and 1,3,5-trimethyl triazine. The data collected in the Troy sponsored study clearly demonstrate that cleavage occurs among the carbon-nitrogen bonds. This pathway cleaves the triazine ring and results in formaldehyde and monoethanolamine (MEA). Another key finding is that dilute solutions of HHT are rapidly degraded. Accordingly, any environmental fate, toxicity or exposure studies performed with dilute solutions of HHT will actually be testing a mixture of formaldehyde and MEA. Since there is a substantial safety data base for both formaldehyde and MEA any further testing on HHT will not provide any additional or useful information.

A summary of the hydrolysis/degradation study mentioned above is attached. A complete copy of the study will be submitted through front-end processing. Please note that the study was conducted using nuclear magnetic resonance (NMR). Previous chemistry studies showed that methods specific for formaldehyde (e.g. dinitrophenyl hydrazine derivatization) or high-performance liquid chromatograph (HPLC) are not suitable for the detection of HHT since they destroy the products equilibrium with formaldehyde, resulting in an inaccurate assessment of HHT and its degradates. NMR was chosen due to its non-destructive nature and its ability to capture the true behavior of HHT and formaldehyde.

An agenda for the meeting is also attached.

Sincerely,

Eliot Harrison,
On behalf of Troy Chemical, Lonza Inc,
Stepan Company, Buckman Laboratories,
Surety Laboratories

Agenda for Meeting Between Registrants of Hexahydro-1,3.5-tris (2-hydroxymethyl)-s-triazine (HHT) and Antimicrobials Division Regarding the GDCI for HHT

Date/Time: To be determined
Participants: Buckman Laboratories, Lonza Inc., Troy Chemical Company, Stepan Company and Surety Laboratories

Agenda

1. Recent chemistry studies on HHT
   - Description of the studies
   - Results of the studies

2. Implication of the Chemistry Studies for HHT Testing and Assessments
   - GDCI studies based on pathway outlined in Final Work Plan (FWP)
   - Chemistry studies do not support this pathway
   - Need for conducting GDCI studies if alternative pathway is correct

3. Responding to GDCI
   - Submission of complete chemistry study
   - Waiver requests
   - Amend FWP and reissue GDCI?

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C 20460

August 24, 2016

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

TROY CORPORATION
TROY CHEMICAL CORPORATION
8 VREELAND ROAD
PO.BOX : 955
FLORHAM PARK, NJ 07932-0955

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 09-AUGUST-2016. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

We are unable to accept your data submittal for further processing and review, because of the significant deficiencies noted below. It is being returned to you for correction. If deficiencies were found which apply to your overall submission, they are described immediately following this paragraph. If problems are found with individual studes, they are described below linked to the study identifier found on the enclosed copy of your bibliography.

49989801

* The following page(s) in this study is/are illegibledue to the poor quality of the photocopying:__6,_11,_33_&_34__.

TROY CORPORATION

August 7, 2016

Document Processing Desk (DCI/AD)
Attention: Reevaluation Team Leader, PM36
U.S. EPA (7510P)
One Potomac Yard (South Building)
2777 S. Crystal Drive
Arlington, VA. 22202

RE: GDCI-083301-1554
Case 3074
Hexahydro-1,3,5-tris(2-hydroxyethyl)-s-triazine
90-Day Data Call-In Response

Dear Sir or Madam:

Troy Chemical Corporation provides the 90-Day Data Call-In (DCI) response for the compound Hexahydro-1,3,5-tris(2-hydroxyethyl)-s-triazine. As part of our 90-Day response we enclose the following information:

- Data Call-In Response Form
- Requirements Status and Registrant's Response including attachments
- Four (4) copies of the following study:
  HHT Hydrolysis-Evidence on Dissociation, June 3, 2016. Krygsman, A. and S. Schuchardt. Fraunhofer Institute for Toxicology and Environmental Medicine (ITEM). Laboratory Project ID. HHT.2016.Dissoc. TCC Reg. No. 2819 47 pages.

  MRID No.: **49989801**

Troy is supplying this information to illustrate the hydrolytic and dissociation breakdown of the HHT molecule and this effect on DCI requested studies. Troy is currently involved in the preparation of protocols for DCI requested studies using NMR technology. Studies are currently underway testing the feasibility of NMR analytical methods for the measurement of the active ingredient HHT in inhalation toxicity studies. Prior to conducting all studies protocols will be provided to the Agency for review and approval.

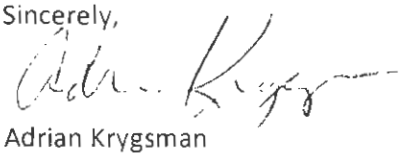
8 Vreeland Road • PO Box 955 • Florham Park, NJ 07932-0955
Tel 973-443-4200 Fax 973-443-0258

Troy is also an active member of the ACC Biocides Panel Antimicrobial Exposure Task Force II (AEATFII) and will rely on information obtained from panel studies to address Agency exposure concerns.

Finally, in order to discuss this new data and its relationship to DCI data requirements Troy and other HHT registrants have requested a meeting with Agency staff. As with the 2008 RED it is important to understand the implications of formaldehyde and its role in the toxicity of HHT and on DCI data requirements.

Should you have any questions concerning this response please contact me via email or phone (email: krygsmaa@troycorp.com or phone: 973-443-4200, X2249). Thank you.

Sincerely,



Adrian Krygsman
Director, Product Registration

United States Environmental Protection Agency
Washington, D.C. 20460
DATA CALL-IN RESPONSE

OMB Approval 2070-0174
EPA FORM 6300-4

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form.
Use additional sheet(s) if necessary.

1. Company Name and Address	2. Case # and Name	3. Date and Type of DCI and Number
TROY CHEMICAL CORP 8 VREELAND ROAD FLORHAM PARK, NJ 079324200	3074 - Hexahydro-1,3,5-tris(2-hydroxyethyl)-s-triazine Chemical # and Name: 083301 Hexahydro-1,3,5-tris(2-hydroxyethyl)-s-triazine	06-May-2016 GENERIC ID # GDCI-083301-1554

4. EPA Product Registration	5. I wish to cancel this product registration voluntarily	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data Requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is an MUP and I agree to satisfy the MUP requirement on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirement on the attached form entitled "Requirements Status and Registrant's Response."
5383-148			X	N/A	N/A

8. Certification: I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative: [signature] / DIRECTOR, PROD. REG.

9. Date: 8/2/16

10. Name of Company: TROY CHEMICAL CORP.

11. Phone Number: 973-443-4200

United States Environmental Protection Agency
Washington, D.C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

OMB Approval 2070-0174
EPA FORM 6300-3

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	Terrestrial and Aquatic Nontarget Organisms Data Requirements (Conventional Chemical)									
850.1300	Daphnid chronic toxicity test	(8)	N				X,Y,Z	TGAI	12	9
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870.6200	Neurotoxicity screening battery	(6, 8, 14)	Y				X,Y,Z	TGAI	12	9
870.7485	Metabolism and pharmacokinetics	(8)	N				X,Y,Z	PAIRA	24	9
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Signature and Title of Company's Authorized Representative: [signature] / DIRECTOR PROD. REG.

11. Date: 8/5/2016

12. Name of Company: TROY CHEMICAL CORPORATION

13. Phone Number: 973-443-4200

United States Environmental Protection Agency
Washington, D.C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

OMB Approval 2070-0174
EPA FORM 6300-3

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company Name and Address	2. Case # and Name	3. Date and Type of DCI and Number
TROY CHEMICAL CORP 8 VREELAND ROAD FLORHAM PARK, NJ 079324200	3074 - Hexahydro-1,3,5-tris(2-hydroxyethyl)-s-triazine Chemical # and Name: 083301 Hexahydro-1,3,5-tris(2-hydroxyethyl)-s-triazine	06-May-2016 GENERIC ID # GDCI-083301-1554

4. Guideline Requirement Number	5. Study Title		PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
835.1110	Activated sludge sorption isotherm	**(5, 8, 11)**	N				X,Y,Z	COMMENT	12	9
835.1230	Sediment and soil absorption/desorption for parent and degradates	**(5, 8)**	N				X,Y,Z	COMMENT	12	9
835.2120	Hydrolysis of parent and degradates as a function of pH at 25 C	**(5, 8)**	N				X,Y,Z	COMMENT	12	1
835.3110	Ready biodegradability	**(1, 5, 8)**	N				X,Y,Z	COMMENT	12	9
835.3220	Porous pot test	**(1, 5, 8)**	N				X,Y,Z	COMMENT	12	9
835.3240	Simulation Test-Aerobic Sewage Treatment-Activated Sludge	**(1, 5, 8)**	N				X,Y,Z	COMMENT	12	9
835.3280	Simulation Tests to Assess the Biodegradability of Chemicals	**(1, 5, 8)**	N				X,Y,Z	COMMENT	12	9
835.4300	Aerobic aquatic metabolism	**(5, 8)**	N				X,Y,Z	COMMENT	24	9
850.3300	Modified Activated Sludge, Respiration Inhibition Test	**(5, 8, 10)**	N				X,Y,Z	COMMENT	12	9

United States Environmental Protection Agency
Washington, D.C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

OMB Approval 2070-0174
EPA FORM 6300-3

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1. Company Name and Address	2. Case # and Name	3. Date and Type of DCI and Number
TROY CHEMICAL CORP 8 VREELAND ROAD FLORHAM PARK, NJ 079324200	3074 - Hexahydro-1,3,5-tris(2-hydroxyethyl)-s-triazine Chemical # and Name: 083301 Hexahydro-1,3,5-tris(2-hydroxyethyl)-s-triazine	06-May-2016 GENERIC ID # GDCI-083301-1554

4. Guideline Requirement Number	5. Study Title		PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
850.4500	Algal Toxicity	**(7, 8)**	N				X,Y,Z	TGAI	12	9
850.4550	Cyanobacteria (Anabaena flos-aquae) Toxicity	**(7, 8)**	N				X,Y,Z	TGAI	12	9
875.1200	Dermal exposure--Indoor	**(8, 12, 14)**	Y				X,Y,Z	TEP	24	2
875.1400	Inhalation exposure--indoor	**(2, 8, 12, 14)**	Y				X,Y,Z	COMMENT	24	2
875.1700	Product Use Information	**(8)**	N				X,Y,Z	TEP	12	1
875.2400	Dermal exposure	**(3, 8, 14)**	Y				X,Y,Z	TEP	24	9
875.2500	Inhalation exposure	**(2, 8, 9, 14)**	Y				X,Y,Z	COMMENT	24	1
SS-1218	Nature of Residue on Surfaces	**(4, 8, 14)**	Y				X,Y,Z	TGAI	24	9
SS-Migration	Migration studies	**(4, 8, 13, 14)**	Y				X,Y,Z	TEP	12	1

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FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 3074 - Hexahydro-1,3,5-tris(2-hydroxye
DCI Number: GDCI-083301-1554

Key: Residue of Concern = Residue of Concern; TEP = Typical End Use Product [TEP]; TGAI = Technical Grade Active Ingredient [TGAI]; TGAI/PAIRA = Technical Grade of the Active Ingredient or Pure Active Ingredient, Radio Labelled; TGAI, TEP = Technical Grade of the Active Ingredient or Technical End-Use Product; TGAI/PAI = Technical Grade Active Ingredient, Pure Active Ingredient

Use Categories Key:

X - Materials preservatives

Y - Industrial processes and water systems - once through

Z - Industrial processes and water systems - not once through

Footnotes: The following footnotes are referenced in column two (5. Study Title) of the Requirements Status and Registrant's Response form. These footnotes apply in addition to any test notes included in 40 CFR Part 158 with respect to the particular data requirement.

1 The results of the Activated Sludge, Respiration Inhibition Test (ASRI), GLN 850.3300, will determine which of the four biodegradation tests are required.
*If the ASRI test results in an EC50 of less than or equal to 20 mg/L, then either the (i) Simulation tests to assess the biodegradability of chemicals discharged in wastewater, GLN 835.3280, (ii) the Simulation Test *Aerobic Sewage Treatment -*A. Activated Sludge Units, GLN 835.3240, or (iii) the Porous Pot Test, GLN 835.3220 is required.
*If the ASRI test results in an EC50 greater than 20 mg/L, then the registrant is required to conduct either the (i) Ready Biodegradability, GLN 835.3110, (ii) Simulation tests to assess the biodegradability of chemicals discharged in wastewater, (iii) the Simulation Test *Aerobic Sewage Treatment *A. Activated Sludge Units, or (iv) the Porous Pot Test.
*If the Ready Biodegradability Study is conducted and passes, then no further testing is required. If, however, the pesticide fails the Ready Biodegradability study, then the (i) Simulation tests to assess the biodegradability of chemicals discharged in wastewater, (ii) the Simulation Test *Aerobic Sewage Treatment *A. Activated Sludge Units, or (iii) the Porous Pot Test is required.

2 TEP and degradate: formaldehyde.

3 Required for manufacturing settings of material preservatives uses only.

4 Required for hard surface cleaner and dish detergent material preservative uses only.

5 Parent TGAI and degradate: 1,3,5-trimethyl triazine.

6 Only Acute (study due 12 months after receipt of DCI) neurotoxicity study is required.

7 On June 27, 2012, EPA announced certain revisions in harmonized guideline series 850 * Ecological Effects Tests * including renumbering and other designations or changes for some guideline studies. See *Final Test Guidelines; OCSPP 850 Series; Notice of Availability* 77 FR 38282, June 27, 2012. http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0154-0028

8 Information on the degradate 1,3,5-trimethyl triazine which remains after the release of formaldehyde may potentially be available from information on other triazines. The registrants could propose triazine data and bridging information if appropriate in lieu of guideline studies on the degradate.

9 Formaldehyde inhalation exposures are expected to occur to as a result of HHT material preservative (household cleaner, paint, detergent, and oil field) application. Currently, no data are available to assess these exposures, and therefore, monitoring data are needed.

10 EPA published draft guidance under guideline 850.6800 and has since published final guidance for this study under guideline 850.3300: http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0154-0021. OECD Test Guideline 209 can also be used as guidance for this study, available online at http://www.oecd-ilibrary.org/content/book/9789264070080-en.

11 EPA has a published final guideline for this study: http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0152-0003.

12 Data required on exposure scenarios: Machinist, Brush/Roller, Airless Sprayer, Mop, Spray and Wipe, Liquid Pour, and Solid Pour WP.

13 Based on the results of the nature of the residue on surfaces study, if residues of concern are identified, then migration studies are required and protocols must be approved by the Agency prior to the initiation of the study.

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FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

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Key: Residue of Concern = Residue of Concern; TEP = Typical End Use Product [TEP]; TGAI = Technical Grade Active Ingredient [TGAI]; TGAI/PAIRA = Technical Grade of the Active Ingredient or Pure Active Ingredient, Radio Labelled; TGAI, TEP = Technical Grade of the Active Ingredient or Technical End-Use Product; TGAI/PAI = Technical Grade Active Ingredient, Pure Active Ingredient

14 A protocol must be submitted to the agency prior to conducting the study.

ATTACHMENT TO REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORM
GDCI-083301-1554

Registrant: Troy Chemical Corporation
Active Ingredient: Hexahydro-1,3,5-tris(2-hydroxyethyl)-s-triazine

Troy Chemical Corporation is requesting data waivers for several of the studies listed in the Generic Data Call-In (GDCI) for hexahydro-1,3,5-tris(2-hydroxyethyl)-s-triazine (HHT). The specific data requirements that waivers are being requested are discussed below. In addition, comments are being provided regarding some of the data requirements for which studies will be submitted.

Environmental Fate and Non-Target Organism Data Requirements

Data waivers are being requested for the following studies:

Guideline Number	***Study Title***
835.1110	Activated sludge sorption isotherm
835.1230	Sediment and soil absorption/desorption for parent and degradates
835.2120	Hydrolysis of parent and degradates as a Function of pH at 25°C
835.3110	Ready biodegradability
835.3220	Porous pot test
835.3240	Simulation test- Aerobic sewage treatment – activated sludge
835.3280	Simulation tests to assess the biodegradability of chemicals
835.4300	Aerobic aquatic metabolism
850.3300	Modified activated sludge, Respiration inhibition test
850.4400	Aquatic plant toxicity using Lemna
850.1300	Daphnid chronic toxicity test

850.1400 Fish early life-stage toxicity test

Basis for Waivers

As discussed in the submission provided to the Agency on July 11, 2016 (attached), HHT is expected to rapidly degrade upon aqueous dilution. The predominant degradates are monoethanolamine and formaldehyde. The substance 1,3,5-trimethyl triazine does not result from the degradation of HHT. Accordingly, the substances present in the environment from the use of HHT will be monoethanolamine and formaldehyde (minor degradates, methanol and 1,3-oxazolidine, might also be present). Therefore, the requested environmental fate and ecotoxicity studies would be actually be testing a mixture of monoethanolamine and formaldehyde, not HHT or 1,3,5-trimethyl triazine. Since there is an ample environmental fate and ecological effects database on monoethanolamine and formaldehyde, conducting additional studies with this mixture will not provide any useful additional data.

The degradation behavior of HHT was evaluated in the hydrolysis study with metal working fluids that was previously submitted to the Agency (MRID No. 48741001) and the study recently submitted by Troy Chemical Company ("HHT Hydrolysis –Evidence on Dissociation"). If there are any issues that remain regarding the degradation of HHT and the resulting degradates these can be addressed in a follow-up hydrolysis study. In this situation, the Agency should reserve the GDCI environmental fate studies until a final determination is made regarding the degradation behavior of HHT.